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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

TUNG, P

ART UNIT

PAPER NUMBER

1652

DATE MAILED:

07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/478,598

Applicant(s)
Rao et al.

Examiner
Peter Tung

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 54-118 is/are pending in the application.

4a) Of the above, claim(s) 84-96 and 108-114 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 54-83, 97-107, and 115-118 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

20) ☐ Other:

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DETAILED ACTION

1. Claims 54-118 are pending.
2. Applicant's election with traverse of Group I, claims 54-57, 117 and 118 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the subject matter of Group I and II encompass the same subject matter and would not require an undue burden of search.

Accordingly, Groups I and II have been rejoined.

3. Claims 84-96 and 108-114 are withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 54-83, 97-107 and 115-118 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation.

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Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. As antibodies only require a minimum of 5 amino acids to recognize an epitope and antibodies will bind denatured epitopes, the use of antibody binding as a general method to confirm a protein's native conformation is not supported by the prior art. A large amount of experimentation would be required to identify antibodies which are unique to a native conformation which can be used to verify the native conformation of a protein. As a native protein has a large number of epitopes, identifying a specific epitope that can function as an indicator of the overall conformation of the protein is unpredictable and would require a large amount of experimentation. Insufficient guidance is provided on how to determine which epitopes are suitable reporters of protein conformation. A large amount of experimentation would be required to determine which epitopes are suitable as reporters of a protein's conformation. Insufficient guidance is provided on what extent of binding by a molecule capable of binding would be required to indicate that an engineered protein has the same conformation as the native protein. The specification does not provide sufficient guidance on using binding molecules to indicate that such molecules are able to distinguish between a native and non-native conformation. Undue experimentation would be required to practice the instant invention based upon the instant disclosure.

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 57-60, 66, 67, 73-75, 81, 82, 98-100, 106, 107, 115 and 116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "dimerizing proteins" in claim 57 is a relative term which renders the claim indefinite. The term "dimerizing proteins" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification does not teach any dimerizing proteins. If "dimerizing proteins" are meant to be antibodies, such a description of antibodies is incorrect because while antibodies are capable of binding two epitopes, dimerization of the bound protein does not necessarily occur.

9. Claims 58, 59, 66, 67, 73-75, 81, 82, 98, 99, 106, 107 and 115 are unclear as to how the "essential" amino acids are essential to the protein. It is understood that such amino acids are "nutritionally" essential amino acids.

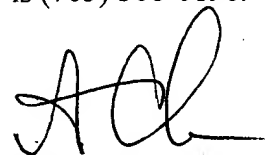
10. Claims 60, 100 and 116 are indefinite because they depend upon an indefinite base claim.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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